

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO. FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/970,969 10/03/2001		Jonathan F. Tait	UOFW117625	3199	
26389	7590 12/11/2003		EXAMINER		
	SEN, O'CONNOR, JOH	HUFF, SHEELA JITENDRA			
1420 FIFTH AVENUE SUITE 2800			ART UNIT	PAPER NUMBER	
SEATTLE, WA 98101-2347			1642		
			DATE MAILED: 12/11/2003	/; <	

Please find below and/or attached an Office communication concerning this application or proceeding.

			Application No.		Applicant(s)				
Office Action Summary			09/970,969		TAIT ET AL.				
			Examiner		Art Unit				
			Sheela J Huff		1642				
Period fo	The MAILING DATE of this commu r Reply	nication appe	ears on the cover	sheet with the c	orrespondence add	iress			
THE N - Exter after - If the - If NO - Failui - Any r	ORTENED STATUTORY PERIOD MAILING DATE OF THIS COMMUN asions of time may be available under the provisior SIX (6) MONTHS from the mailing date of this comperiod for reply specified above is less than thirty period for reply is specified above, the maximum are to reply within the set or extended period for repeply received by the Office later than three months dipatent term adjustment. See 37 CFR 1.704(b).	NICATION.  ns of 37 CFR 1.136  nmunication.  (30) days, a reply obtained with the common statutory period with will, by statute, or common statute	6(a). In no event, howe within the statutory min ill apply and will expire cause the application to	ever, may a reply be tim imum of thirty (30) days SIX (6) MONTHS from to become ABANDONED	ely filed s will be considered timely the mailing date of this co D (35 U.S.C. § 133).	mmunication.			
1)[	Responsive to communication(s) fi	led on	<u>.</u> .						
2a) <u></u> □	☐ This action is <b>FINAL</b> . 2b) ☑ This action is non-final.								
3)□	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.								
Dispositi	on of Claims								
4)🛛	Claim(s) <u>21-38</u> is/are pending in the application.								
	4a) Of the above claim(s) is/are withdrawn from consideration.								
5)⊠	☑ Claim(s) <u>22-27</u> is/are allowed.								
·	Claim(s) <u>21,28,32 and 36-38</u> is/are rejected.								
·	Claim(s) <u>29-31 and 33-35</u> is/are ob	•							
,	Claim(s) are subject to restr	iction and/or	election require	ment.					
	on Papers								
•	The specification is objected to by t								
10)	The drawing(s) filed on is/ard	•		•					
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
141	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).								
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.									
Priority under 35 U.S.C. §§ 119 and 120  12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).									
a)( 13)	All b) Some * c) None of:  1. Certified copies of the priorit  2. Certified copies of the priorit  3. Copies of the certified copies application from the Internation and the attached detailed Office action and the certific reference was included to the certific reference was included to the foreign lands and the certification of the foreign lands acknowledgment is made of a claim acknowledgment is made of a claim afterence was included in the first second certification.	y documents y documents s of the priori ional Bureau ion for a list o for domestic ed in the first anguage prov	have been received have been rec	eived.  sived in Application  ave been receives  (a)).  pies not receive  5 U.S.C. § 119(e)  specification or  on has been receive  5 U.S.C. §§ 120	on No  d in this National and the control of	application) Data Sheet. a specific			
	e of References Cited (PTO-892)		4) 🔲	Interview Summary	(PTO-413) Paper No(s	·) ·			
2) Notic	e of Draftsperson's Patent Drawing Review nation Disclosure Statement(s) (PTO-1449)		5) 🔲		atent Application (PTO				

Art Unit: 1642

#### **DETAILED ACTION**

Claims 21-38 are pending.

### Information Disclosure Statement

The IDS filed 10/3/01 has been considered and an initialed copy of the PTO-1449 is enclosed.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 339285 or Saino et al US 5591633.

The EP discloses the sequence in Figure 1 which has about 99% similarity to SEQ ID NO. 1, 3 and 5 (see attached sequence alignments). It is inherent that this sequence will hybridize to the complement strand of that in the reference and that the complement of the strand in the reference will hybridize to the sequence of the instant invention.

Saino et al discloses SEQ ID No. 2 which has about 99% similarity to SEQ ID NO. 1, 3 and 5 (see attached sequence alignments). It is inherent that this sequence will hybridize to the complement strand of that in the reference and that the complement of the strand in the reference will hybridize to the sequence of the instant invention.

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# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 21, 28 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/04294 or Kasina et al US 5968477 in view of Giblin et al Bioconjugate Chem. vol. 8 p. 347 (1997)..

WO98/04294 and Kasina et al US 5968477 are related in the US patent is the priority document in the WO. Only the WO will be discussed in detail, since both references are the same. The WO discloses a modified annexin, preferably annexin V, that can be made recombinantly (pages 4 and 7 bottom), wherein the modification is at the N-terminus and comprises the addition of amino acid residues (at lest one of which provides an accessible sulfhydryl) (page 8, lines 5-10) and, preferably the sulfhydryl is cysteine (page 9, lines 3-8). Furthermore, the amino acids residues in the N-terminus modification can include gly (page 20, lines 9). Examples VIII-X disclose specific methods for making a modified annexin recombinantly.

The primary references do not disclose the chelation moiety to contain a glycine or to be cys-gly-cys.

Giblin et al disclose the chelate moiety N-acetyl-cys-gly-cys-gly complexed with Rhenium and conjugated to alpha-melanotropin. See abstract and entire reference.

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In view of the fact that annexin, especially annexin V, can readily be modified at the amino terminus to contain a short peptide which functions as a chelating moiety and since the short peptide needs to include a cys and can be made recombinantly and since Giblin et al clearly shows that N-acetyl-cys-gly-cys-gly is a known chelating moiety, it would have been obvious to one of ordinary skill in the art at the time of the invention it to any known chelating moiety to complex the radionuclide to annexin.

Discerning the nucleic acid sequence for the Giblin et al chelation moiety is within the purview of one skilled in the art. Thus, it would have been obvious to chelate N-acetyl-cys-gly-cys-gly to the amino terminus of annexin V with the expected benefits of producing imaging or radioisotope delivery.

Claims 21, 28 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/04294 or Kasina et al US 5968477 in view of Dean et al (filed 3/31/95).

WO98/04294 and Kasina et al US 5968477 are related in the US patent is the priority document in the WO. Only the WO will be discussed in detail, since both references are the same. The WO discloses a modified annexin, preferably annexin V, that can be made recombinantly (pages 4 and 7 bottom), wherein the modification is at the N-terminus and comprises the addition of amino acid residues (at lest one of which provides an accessible sulfhydryl) (page 8, lines 5-10) and, preferably the sulfhydryl is cysteine (page 9, lines 3-8). Furthermore, the amino acids residues in the N-terminus modification can include gly (page 20, lines 9). Examples VIII-X disclose specific methods for making a modified annexin recombinantly.

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The primary references do not disclose the chelate moiety to contain a glycine and a cysteine or to be cys-gly-gly.

Dean et al disclose the chelation of Tc-99m, Re-186 or Re-188 through gly-gly-cys and cys-gly-gly to VIP peptides (see col. 8 lines 62+, col. 6 lines 30+).

In view of the fact that annexin, especially annexin V, can readily be modified at the amino terminus to contain a short peptide which functions as a chelating moiety and since the short peptide needs to include a cys and since this can be made recombinantly and since Dean et al clearly shows that cys-gly-gly is a known chelating moiety, it would have been obvious to one of ordinary skill in the art at the time of the invention it to any known chelating moiety to complex the radionuclide to annexin.

Discerning the nucleic acid sequence for the Dean et al chelation moiety is within the purview of one skilled in the art. Thus, it would have been obvious to chelate cys-gly-gly to the amino terminus of annexin V with the expected benefits of producing imaging or radioisotope delivery.

## Allowable Subject Matter

Claims 22-27 are allowed.

Claims 29-31 and 33-35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J Huff whose telephone number is 703-305-

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7866. The examiner can normally be reached on Tuesday 5:30am-11:30am and Fridays 6:00am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Sheela J Huff Primary Examiner

Art Unit 1642

sjh

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MOLECULE TYPE: DNA (genomic)
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APPLICANT: SAINO, YUSHI
APPLICANT: SAINO, YUSHI
APPLICANT: UNASATI AKIO
APPLICANT: UNASATI AKIO
TITLE OF INVENTION: ANTICOAGULANT POLYPEPTIDE
NUMBER OF SEQUENCES:
5
CORRESPONDENCE ADDRESS:
ADDRESSE: OBLON, SPIVAK, MCCLELLAND, WAIER & NEUSTADT,
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            SOFTWARE: Patentin Release #1.0, Version #1.25
CURRENT APPLICATION DATA:
APPLICATION NUMBER: US/08/125,746
FILING DATE: 4-SEP-1993
CLASSIFICATION 530
PRIOR APPLICATION TAR:
APPLICATION NUMBER: US/08/7,623
FILING DATE: 13-DEC-1991
PRIOR APPLICATION NUMBER: US/07/807,623
FILING DATE: 13-DEC-1991
PRIOR APPLICATION NUMBER: US/07/807,623
FILING DATE: 20-FEB-1987
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FILING DATE: 23-JUL-1987
ATTORNEY/AGENT INFORMATION:
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REFERENCE/DOCKET NUMBER: 80-074-0
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COMPUTER: IBM PC compatible
OPERATING SYSTEM: PC-DOS/MS-DOS
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Patent No. 5591633
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TELEFAX: (703) 413-220
TELEX: 248855 OPAT UR
INFORMATION FOR SEQ ID NO: 2:
SEQUENCE CHARACTERISTICS:
LENGTH: 1567 base pairs
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Pred, No. 1.8e-276;
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TYPE: nucleic acid
STRANDEDNESS: unkno
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         APPLICANT: Skeiky, Yasir A.W.
APPLICANT: Henderson, Robert A.
APPLICANT: MCNeill, Patricia D.
TITLE OF INVENTION: COMPOSITIONS AND METHODS FOR THE THERAPY
FITLE OF INVENTION: AND DIAGNOSIS OF LUNG CANCER
FILE REFERENCE: 210121.455C11
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Wang, Aijun
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US-09-643-597-261
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1755 S. Jefferson Davis Highway, Suite 400
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pred. No. 1.1e-275;
0; Mismatches 2;
                                                                                                                                                                                                                                                                                                                                                           SOFTWARE: Patentin Release #1.0, Version #1.25 CURRENT APPLICATION DATA:
                                                                                                                               APPLICANT: SAINO, YUSHI
APPLICANT: IMASAKI, AKIO
APPLICANT: INASAKI, AKIO
APPLICANT: SODA, MAKOTO
APPLICE OF INVENTION:
NUMBER OF SEQUENCES: 5
                                                                                                                                                                                                                                                                                                                                                                                 PRICE TO NUMBER: US/08/125,746
FILING DATE: 24-SEP-1993
CLASSIFICATION: 530
PROOF APPLICATION DATA
APPLICATION NUMBER: US 07/807,623
FILING DATE: 13-DEC-1991
PRIOR APPLICATION DATA:
APPLICATION NUMBER: JP 037227/1987
FILING DATE: 20-FEB-1987
PRIOR APPLICATION DATA:
APPLICATION NUMBER: JP 184428/1987
FILING DATE: 23-JUL-1987
ATTORNEY/AGENT INFORMATION:
                                                                                                                                                                                                               MCCLELLAND,
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          80-074-0
                                                                                                                                                                                                                                                                                                                                 COMPUTER: IBM PC compatible OPERATING SYSTEM: PC-DOS/MS-DOS
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              NAME: Oblon, No. 5591633man F. REGISTRATION NUMBER: 24,618
                                                                                           Sequence 4, Application US/08125746 Patent No. 5591633
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        REFERENCE/DOCKET NUMBER: 80
TELECOMMUNICATION INFORMATION:
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        MOLECULE TYPE: DNA (genomic)
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Best Local Similarity 99.8%;
Matches 955; Conservative
                                                                                                                                                                                                  CORRESPONDENCE ADDRESS:
ADDRESSEE: OBLON, SPIVAK,
                                                                                                                                                                                                                                                                                                         COMPUTER READABLE FORM:
MEDIUM TYPE: Floppy disk
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248855 OPAT UR
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nucleic acid
EDNESS: unknown
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                                                                                                                       GENERAL INFORMATION:
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STREET: 17
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107..1066
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(first entry)
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                                                                                                                                                                                                                                                                                                                                                                                      which inhibits blood coagulation as an antiinflammatory agent
                                                                                                                                                                                                                                                                                                                                                                                                                                                                             Score 956.8; DB 10; Length 1605;
Pred. No. 1.1e-267;
0; Mismatches 2; Indels 0;
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and phospholipase A2 and is used
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                                                                                        AAN91821 standard; DNA; 1605
                                                                                                                                                                       Placenta; blood coagulation
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Local Similarity 99.8%;
es 958; Conservative
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(first entry)
                                                                                                                                                       Endonexin II complete cDNA
                                                                                                                                                                                          Homo sapiens (human).
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P-PSDB; AAP91021.
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16-MAR-1990
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                              582 ATTGAGGAAACCATTGACGGGAGACTTCTGGCAATTTAGAGCAACTACTCCTTGCTGTT
                                                                         CGAAGTGTGTCTCATTTGAGAAAGGTGTTTGACAAGTACATGACTATATCAGGATTTCAA
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                NA sequence encoding anticoagulant PP4 protein new recombinant protein, vectors, antibodies, etc.,
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             DNA sequence encoding anticoagulant PP4 protein. inhibits blood coagulation at the thromboplastin the derived protein is 320 amino acids. (Updated on 25-MAR-2003 to correct PF field.) (Updated on 25-MAR-2003 to correct PF field.)
                                                                                                                                                                                                                                                                                                                                                                                                 Anticoagulant; PP4 protein; thromboplastin.
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Pred. No. 6.3e-268;
0; Mismatches 2;
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         sapiens (human).
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P-PSDB; AAP91021.
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